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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,486	02/24/2004	Russell A. Houser	019	1784

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EXAMINER	
BACHMAN, LINDSEY MICHELE	

ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/785,486	HOUSER ET AL.	
	Examiner	Art Unit	
	Lindsey Bachman	3734	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-23,35-48 and 50-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-23,35-48 and 50-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 August 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's Request for Continued Examination filed 15 October 2007.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 21-23, 27-31, 33, 35, 36, 39, 45-48, and 52-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Gittings et al. (US Patent 7,025,773).

Claim 21, 22, 23, 27, 28, 36: Gittings'773 teaches a device (26) that contains a layer of biocompatible material (column 7, lines 15-24) and a layer of shape memory material (Nitinol) having an upper side (outside surface of tube) and lower side (inside surface of tube), the sheet consisting of a single piece of material (column 7, lines 8-15). The liner is attached to at least a portion of the upper side and the lower side without the use of an adherent material (column 7, lines 25-31; at least weaving the liner through the stent elements meets the claim limitations). The shape memory material is configured to be curved.

Claim 29, 30 and 35: The device taught by Gittings'773 is capable of compression (of plaque, for example) in the heart.

Claim 31 and 33: Gittings'773 discloses a deployment device (10) for deploying the device that includes a handle (12) and a deployment section (14, 16) configured to retain the device for delivery (see Figure 3). The device contains a surface that is capable of applying a vacuum.

Claim 39, 45, 46, 47, 48, 52, 53: Gittings'773 teaches a method of applying a medical device to a tissue surface within a body that includes retaining the medical device (26) to a deployment device (as shown in Figure 1; also column 10, line 63 to column 11, line 19), advancing the deployment device to the tissue surface (Figure 5a, 5b), pressing the medical device against the tissue surface (TV=target vessel in Figures 5a-5d, denotes a blood vessel/heart as stated in abstract) (column 11, lines 5-19) and manipulating the deployment device to separate the deployment device from the medical device and leaving it against the tissue surface (column 11, line 53-60). The medical device contains a layer of biocompatible material (column 7, lines 15-24) and a layer of shape memory material (Nitinol) having an upper side (outside surface of tube) and lower side (inside surface of tube), the sheet consisting of a single piece of material (column 7, lines 8-15). The liner is attached to at least a portion of the upper side and the lower side without the use of an adherent material (column 7, lines 25-31; at least weaving the liner through the stent elements meets the claim limitations). The shape memory material is configured to be curved. The deployment device (10) includes a

handle (12) and a deployment section (14, 16) configured to retain the device for delivery (see Figure 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 25 and 37 and 38 are rejected under 35 U.S.C. 103(a) as being obvious over Gittings'773, as applied to Claim 21 and 36, respectively, in further view of McNamara et al. (US Patent 6,004,347).

Gittings'773 teaches the limitations of Claim 25 and 37 including a concave shape, but does not teach projections extending from the medical device configured to attach the device to the tissue surface. McNamara'347 teaches that it is known in the art to attach anchors/arms (30) having projections (40) configured to engage the vessel wall (column 5, lines 51-67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Gittings'773 with

projections, as taught by McNamara'347, in order to help attach the stent to the inside surface of the vessel.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gittings'773 in view McNamara'347, as applied to Claim 25, and in further view of Forber, et al. (US Patent 5,733,294).

Gittings'773 in view McNamara'347 disclose the limitations of Claim 26, except for the use of a power source.

Forber'294 discloses an occlusion apparatus with the use of an external electricity source to cause the arms (60) of a device to repel each other (column 6, lines 45-57). It would have been obvious to one skilled in the art at the time the invention was made to combine known prior art elements (use of power to expand a device) according to know methods to use an external electricity source to cause arms to repel each other in order to uniformly distribute themselves.

Claim 32 and 43 is rejected under 35 U.S.C. 103(a) as being obvious over Gittings'773, as applied to Claim 21 and 39, respectively, in further view of Plaia et al. (US Patent 6,090,135).

Gittings'773 teaches the limitations of Claims 32 and 43 except for using a deployment device with jaws.

Plaia'135 teaches that it is known to use a deployment device with jaws (290) (column 14, lines 62 to column 15, lines 14). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute one known

deployment device with another deployment device, such as the forceps taught by Plaia'135, to obtain predictable results.

Claim 34 rejected under 35 U.S.C. 103(a) as being obvious over Gittings'773, as applied to Claim 21, in further view of Narciso, Jr. (US Patent 5,419,760).

Claim 34: Gittings'773 does not teach therapeutic coatings on the stent.

Narciso'760 teaches that it is well known to place drug coatings on a stent in order to treat the tissue/blood at the stent's delivery location. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Gittings'773 with a drug coating, as taught by Narciso'760, in order to deliver drugs to the stent's delivery location.

Claim 40 rejected under 35 U.S.C. 103(a) as being obvious over Gittings'773, as applied to Claim 39, in further view of Sigwart (US Patent 5,443,500).

Gittings'773 teaches the limitations of Claim 45 except for using an adhesive to attach the stent to the delivery device.

Sigwart'500 teaches that it is known to use an adhesive to attach a stent to a delivery device (column 4, lines 64-68). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine known prior art elements taught by Sigwart'500 (adhesive to attach a stent to a delivery device) by known methods with the device taught by Gittings'773 with no change in function to yields predictable results.

Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being obvious over Gittings'773, as applied to Claim 39, in further view of Monroe et al. (US Patent 6,113,608).

Gittings'773 teaches the limitations of Claim 41 and 42 except for the use of a vacuum to retain the medical device on the delivery device or teaching advancing a plunger within the deployment device in order to release the medical device.

Monroe'608 teaches that it is known to attach a stent to a delivery device and to retain it there by using a vacuum (column 3, lines 15-38 and 61-67) and also it is known to deploy a medical device by advancing a plunger (120) (column 3, lines 15-67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Gittings'773 with a deployment device that uses a vacuum and plunger, as taught by Monroe'608 because it is known to substitute one known element with another known element to obtain predictable results.

Claim 44 is rejected under 35 U.S.C. 103(a) as being obvious over Gittings'773, as applied to Claim 39, in further view of McNamara et al. (US Patent 6,004,347).

Gittings'773 teaches the limitations of Claim 44, including deploying the device at the heart, but does not teach projections extending from the medical device configured to attach the device to the tissue surface. McNamara'347 teaches that it is known in the art to attach arms (30) having attachment means (40) configured to engage the vessel wall (column 5, lines 51-67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Gittings'773 with

projections, as taught by McNamara'347, in order to help attach the stent to the inside surface of the vessel.

Claim 45 rejected under 35 U.S.C. 103(a) as being obvious over Gittings'773, as applied to Claim 39, in further view of Narciso'760.

Claim 45: Gittings'773 does not teach therapeutic coatings on the stent.

Narciso'760 teaches that it is well known to place drug coatings on a stent in order to treat the tissue/blood at the stent's delivery location. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Gittings'773 with a drug coating, as taught by Narciso'760, in order to deliver drugs to the stent's delivery location.

Claim 50 is rejected under 35 U.S.C. 103(a) as being obvious over Gittings'773, as applied to Claim 47, in further view of McNamara et al. (US Patent 6,004,347).

Gittings'773 teaches the limitations of Claim 50 except for projections extending from the medical device configured to attach the device to the tissue surface. McNamara'347 teaches that it is known in the art to attach anchors (30) having projections (40) configured to engage the vessel wall (column 5, lines 51-67). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Gittings'773 with projections, as taught by McNamara'347, in order to help attach the stent to the inside surface of the vessel.

Claim 51 is rejected under 35 U.S.C. 103(a) as being obvious over Gittings'773, as applied to Claim 47, in further view of Yang et al. (US Patent 6,517,575).

Gittings'773 teaches the limitations of Claim 51 except for a layer of swellable material on the device.

Yang'575 teaches that it is known to place a layer of swellable material on stents in order to aid in the deformation of the stent (column 1, line 35 and column 2, lines 45-49). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Gittings'773 with the swellable material layer, as taught by Yang'575, because it aids in deforming the stent.

Response to Arguments

Applicant's arguments with respect to claims 21-23, 25-48, and 50-53 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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SPE 3731

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